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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/566,056
	Filing Date	January 25, 2006
	First Named Inventor	Bruce E. Reidenberg
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	Attorney Docket Number	02755/100J553-US1

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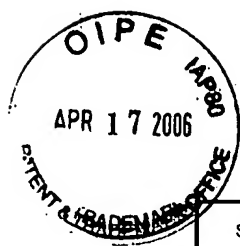
It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: April 17, 2006

Respectfully submitted,

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		Art Unit	N/A		
		Examiner Name	Not Yet Assigned		
Sheet	1	of	3	Attorney Docket Number	02755/100J553-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	US-4,806,341	02-21-1989	Chien et al.	
	2.	US-4,119,713	10-10-1978	Carosio	
	3.	US-5,026,556	06-25-1991	Drust et al.	
	4.	US-5,069,909	12-03-1991	Sharma et al.	
	5.	US-5,225,199	07-06-1993	Hidaka et al.	
	6.	US-5,240,711	08-31-1993	Hille et al.	
	7.	US-5,613,958	03-25-1997	Kochinke et al.	
	8.	US-5,942,530	08-24-1999	Jill Ann Panetta	
	9.	US-20040146547-A1	07-29-2004	Marcenyc et al.	
	10.	US-20040241218-A1	12-02-2004	Lino Tavares	
	11.	US-20040122554-A1	06-24-2004	Howard	
	12.	US-20040126416-A1	07-01-2004	Bruce Reidenberg	

FOREIGN PATENT DOCUMENTS						
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	13.	M.A. NASAR et al., "An Open Study of Sub-lingual Buprenorphine In The Treatment Of Chronic Pain In The Elderly", Curr. Med. Res. Opin. 1986, Vol. 10, No. 4, 1986, pages 251-255	
	14.	G. CAPOGNA et al., "Intrathecal Buprenorphine For Postoperative Analgesia In The Elderly Patient", Anaesthesia, 1988, Vol. 43, pages 128-130	
	15.	K. HANNIBAL, et al., "Preoperative Wound Infiltration With Bupivacaine Reduces Early And Late Opioid Requirement After Hysterectomy", Anesth Analg., 1996, Vol. 83, pages 376-381	
	16.	YOSHIMI INAGAKI et al., "Mode and Site Of Analgesic Action Of Epidural Buprenorphine In Humans", Anesth Analg., 1996, Vol. 83, pages 530-536	

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Sheet	2	of	3	Attorney Docket Number	02755/100J553-US1

17.	P.TAUZIN-FIN et al., "Effect Of Balanced Analgesia With Buprenorphine On Pain Response And General Anesthesia Requirement During Lithotripsy Procedures", <i>European Journal of anesthesiology</i> , 1998, Vol. 15, pages 147-152	
18.	ERIC C. STRAIN et al., " <i>Acute Effects Of Buprenorphine, Hydromorphone and Naloxone In Methadone-Maintained Volunteers</i> ", <i>The Journal Of Pharmacology And Experimental Therapeutics</i> , 1992, Vol. 261, No. 3, pages 985-993	
19.	K. J. SCHUH et al., " <i>Buprenorphine, Morphine and Naloxone Effects During Ascending Morphine Maintenance in Humans</i> ", <i>The Journal of Pharmacology And Experimental Therapeutics</i> , 1996, Vol. 278, No. 2, pages 836-845	
20.	H. ADRIAENSEN et al., "A Long-Term Open, Clinical And Pharmacokinetic Assessment Of Sublingual Buprenorphine In Patients Suffering From Chronic Pain", <i>Acta Anaesthesiologica Belgica</i> , Vol. 36 March 1985, pages 33-40	
21.	PAUL J. DESJARDINS et al., "The Injectable Cyclooxygenase-2-Specific Inhibitor Parecoxib Sodium Has Analgesic Efficacy When Administered Preoperatively", <i>Anesth Analog</i> , 2001, 93, pages 721-727	
22.	SHARON L. WALSH et al., " <i>Acute Administration of Buprenorphine in Humans: Partial Agonist and Blockade Effects</i> ", <i>The Journal Of Pharmacology And Experimental Therapeutics</i> , 1995, Vol. 274, No. 1, pages 361-372	
23.	M. JUHLIN-DANNFELT et al., "Premedication With Sublingual Buprenorphine For Out-Patient Arthroscopy: Reduced Need For Postoperative Pethidine But Higher Incidence Of Nausea", <i>Acta Anaesthesio Scand</i> , 1995, 39, pages 633-636	
24.	RAYMOND A. DIONNE et al., "Suppression Of Postoperative Pain By Preoperative Administration of Ibuprofen In Comparison To Placebo, Acetaminophen, And Acetaminophen, and Acetaminophen Plus Codeine", <i>J. Clin. Pharmacol.</i> , 1983, Vol. 23, pages 37-43	
25.	JOHN MENDELSON et al., " <i>Dose Proportionality of 4, 8, 16 And 32 MG Sublingual Buprenorphine Solutions</i> ", <i>American Society for Clinical Pharmacology and Therapeutics</i> , 1999, 65, (2), 154, Abstract PII-28	
26.	P. J. FUDALA et al., " <i>A Multi-Site Efficacy Evaluation Of A Buprenorphine/Naloxone Product For Opiate Dependence Treatment</i> ", In: Harris, LS (ed). <i>Problems of Drug Dependence</i> , 1998. NIDA Research Monograph #179. Rockville: National Institute On Drug Abuse, 1998a; 105	
27.	ERIC C. STRAIN et al., " <i>Comparison Of Buprenorphine and Methadone In The Treatment Of Opioid Dependence</i> ", <i>The American Journal of Psychiatry</i> , July 1994, 151, 7, pages 1025-1030	
28.	HANNU KOKKI et al., "Comparison of Pre- And Postoperative Administration Of Ketoprofen For Analgesia After Tonsillectomy In Children", <i>Pediatric Anesthesia</i> 2002, 12 (2), pages 162-167	
29.	PINTO PEREIRA et al., "Analgesic Effects Of Diclofenac Suppository And Injection After Preoperative Administration", <i>Int. J. Clin. Pharm. Res.</i> 1999, 19(2): pages 47-51	
30.	A.F. FAPONLE, " <i>Management Of Pain After Surgery - A Short Review</i> ", <i>Nigerian Journal of Medicine</i> Vol. 10, No. 3, pages 112-115	
31.	Abstract, AKATSUKA et al., "The Relief Of Postoperative Pain By Suppositories Of Buprenorphine or NSAID", <i>Masui</i> , 1996, 45(3):298-303	✓

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	32.	Abstract, FLETCHER, "Prevention Of Postoperative Pain", Ann Fr. Anesth Reanim 1998, 17(6), pages 622-632	√
	33.	Abstract, S. TANAKA et al., "Preoperative Fluribiprofen Provides Pain Relief After Laparoscopic Cholecystectomy", Masui, 1997, 46(5), pages 679-683	√
	34.	Abstract, A. COLI et al., "Evaluation Of The Effectiveness of NSAIDs In The Prevention Of Postoperative Pain. Comparison Between Pre- And Postoperative Administration Of Sodium Naproxen In Orthopedic Surgery", Minerva Anesthesiol 1993, 59(10), pages 531-535	√
	35.	Abstract, KAKINOHANA, et al. "Pre-Emptive Analgesia With Intravenous Ketamine Reduces Postoperative Pain In Young patients After Appendectomy: A Randomized Control Study", Masui 2000, 49(10), pages 1092-1096	√
	36.	F. BREMA et al., "Oral Tramadol And Buprenorphine In Tumor Pain. An Italian Multicentre Trial", Int. J. Clin. Pharm. Res XVI, (4/5), 1996, pages 109-116	
	37.	A.B. CIRADO, et al., "Reduction of isoflurane MAC with buprenorphine and morphine in rats" Laboratory Animals., 2000, 34 (3):252-9	

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